UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND RELEVANT PRODUCTS LIABILITY LITIGATION	:	**3:09-md-02100-DRH-CJP** **MDL No. 2100**
COURTNEY C. BLASIUS **Plaintiff**	:	**Judge David R. Herndon** **COMPLAINT AND JURY DEMAND**
vs.	:	**Case No: 3:10-cv-10797-DRH-PMF**
BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER SCHERING PHARMA AG, BAYER CORPORATION, BAYER HEALTH-CARE, LLC, BAYER PHARMACEUTICALS CORPORATION, BERLEX LABORATORIES, INC., BERLEX, INC. and BAYER AG, **Defendants.**	:	

NOW COMES Courtney C. Blasius, by and through her undersigned counsel, LANHAM BLACKWELL, P.A., and complains against Defendants as follows:

Nature of the Action

1. This is an action brought by Plaintiff Courtney C. Blasius ("Plaintiff") for strict product liability, negligence, breach of warranties, and for violation of the Vermont consumer fraud statute, seeking damages associated with her ingestion of the pharmaceutical drug YAZ, an oral contraceptive developed, designed, licensed, manufactured, distributed, sold, and/or marketed by Defendants.

2. As a result of the ingestion of YAZ, Plaintiff has suffered injuries of a temporary and permanent nature, including but not limited to, coronary arrest, anoxic brain injury, permanent disability and emotional distress.

Parties

3. Plaintiff resides in Winooski, Vermont.

4. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC., is and at all times relevant was, a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P. O. Box 1000, Montville, New Jersey 07045-1000.

5. Defendant BAYER SCHERING PHARMA AG, formerly known as Schering AG, is a pharmaceutical company that is organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

6. Defendant BAYER CORPORATION is, and at all times relevant was, a corporation organized under the laws of the State of Indiana with its headquarters and principal place of business at 100 Bayer Rd., Pittsburgh, Pennsylvania 15202.

7. At all times relevant, Defendant BAYER CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Vermont, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptives, YAZ and Yasmin.

8. Defendant BAYER HEALTHCARE, LLC, is, and at all times relevant was, a limited liability corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 100 Bayer Road, Pittsburg, PA 15205.

9. At all times relevant, Defendant BAYER CORPORATION LLC was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Vermont either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptives YAZ and Yasmin.

10. Defendant BAYER HEALTHCARE, LLC is wholly owned by Defendant BAYER CORPORATION.

11. Defendant BAYER PHARMACEUTICALS CORPORATION is, and at all times relevant was, a corporation organized under the laws of the State of Delaware with its headquarters and principal place of business at 1400 Morgan Lane, West Haven, Connecticut.

12. At all times relevant, Defendant BAYER PHARMACEUTICALS CORPORATION was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Vermont, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptives YAZ and Yasmin.

13. As of January 1, 2008, Defendant BAYER PHARMACEUTICALS CORPORATION was merged into Defendant BAYER HEALTHCARE PHARMACEUTICALS INC.

14. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc., and is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

15. At all times relevant, Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including

in the State of Vermont, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptives YAZ and Yasmin.

16. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC. is the holder of the approved New Drug Application ("NDA") for YAZ.

17. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. are, and at all times relevant were, foreign corporations with their headquarters and principal places of business at Montville, New Jersey and with a post office address of P. O. Box 1000, Montville, New Jersey 07045 and places of business located at 6 West Belt Road, Wayne, New Jersey 07470.

18. Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were integrated into Bayer HealthCare AG and operates as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

19. At all times relevant, Defendants BERLEX LABORATORIES, INC. and BERLEX, INC. were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Vermont, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptives YAZ and Yasmin.

20. Defendant BAYER SCHERING PHARMA AG is a corporate successor to Schering AG.

21. Schering AG was renamed BAYER SCHERING PHARMA AG effective December 29, 2006.

22. Defendant BAYER SCHERING PHARMA AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania, 15205.

23. At all times relevant, Defendant BAYER SCHERING PHARMA AG was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Vermont, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptives YAZ and Yasmin.

24. Defendant BAYER SCHERING PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive YAZ.

25. Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

26. Defendant BAYER AG is the parent/holding company of all other named Defendants.

27. Defendant BAYER AG's headquarters and principal place of business in the United States is located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

28. At all times relevant, Defendant BAYER AG was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, including in the State of Vermont, either directly or indirectly through third parties, subsidiaries or related entities, the oral contraceptives YAZ and Yasmin.

29. Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Pharmaceuticals Corporation, Bayer Healthcare Pharmaceuticals, Inc., Berlex Laboratories, Inc. and Berlex, Inc., Bayer Schering Pharma AG, Bayer AG, shall be referred to herein individually by name or jointly as "Defendants."

30. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational

units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

31. At all times herein mentioned, each of the Defendants was the agent, servant, partner, predecessors in interest, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture.

Jurisdiction and Venue

32. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, as there is complete diversity of citizenship between Plaintiff and Defendants, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

33. Venue is proper in the Southern District of Illinois for purposes of pretrial proceedings pursuant to the Judicial Panel on Multidistrict Litigation's October 1, 2009 Transfer Order.

Facts

34. YAZ and Yasmin, known generically as drospirenone and ethinyl estradiol, are a combination birth control pill originally developed by Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC. containing the hormones estrogen and progestin.

35. The estrogen is ethinyl estradiol and the progestin is drospirenone.

36. Combination birth control pills are referred to as combined hormonal oral contraceptives.

37. Yasmin was approved by the FDA in April 2001, and YAZ was approved in October 2006.

38. In 2006, Bayer acquired Defendant BERLEX LABORATORIES, INC. and/or Defendant BERLEX, INC. and began marketing YAZ.

39. The difference between Yasmin/YAZ and other birth control pills on the market is that drospirenone has never before been marketed in the United States and is unlike other progestins available in the United States.

40. YAZ/Yasmin's use of drospirenone, a diuretic, creates unique risks compared to other oral contraceptives and is known to cause medical problems, including severe heart arrhythmias.

41. Upon information and belief, Defendants knew or should have known about the correlation between the use of Yasmin and YAZ and a significantly increased risk of severe heart arrhythmias.

42. Despite the wealth of scientific information available, Defendants ignored the correlation between the use of Yasmin and YAZ and a significantly increased risk of severe heart arrhythmias and still promoted, sold, advertised, and marketed the use of YAZ/Yasmin without sufficient warnings.

43. Defendants were warned at least three times by the FDA in 2003, 2008 and 2009, for misleading the public through the use of ads which overstate the efficacy of Yasmin and YAZ, and minimize the serious risks associated with the drugs.

44. Defendants falsely and fraudulently represented to the medical and healthcare community, to Plaintiff, the FDA, and the public in general, that Yasmin and YAZ had been tested and were found to be safe and/or effective for their indicated use.

45. These false representations were made by Defendants with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense and/or purchase Yasmin and YAZ for use as a contraceptive, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety and welfare of Plaintiff.

46. Defendants knew and were aware or should have been aware that Yasmin and YAZ had not been sufficiently tested, were defective in design and testing, and/or that they lacked adequate and/or sufficient warnings.

47. Defendants knew or should have known that Yasmin and YAZ had a potential to, could and would cause severe and grievous injury and death to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

48. In representations to Plaintiff, her healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

A. That Yasmin and YAZ are not as safe as other available contraceptives;

B. That the risks of adverse events with Yasmin and YAZ were higher than those of other available contraceptives;

C. That the risks of adverse events with Yasmin and YAZ were not adequately tested and/or known by Defendants;

D. That patients needed to be monitored more regularly than normal while using Yasmin and YAZ; and

E. That Yasmin and YAZ were designed, tested, manufactured, marketed, produced, distributed and advertised negligently, defectively, fraudulently and improperly.

49. Defendants were under a duty to disclose to Plaintiff and her physicians, hospitals, healthcare providers and/or the FDA the defective nature of Yasmin and YAZ.

50. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Yasmin and YAZ, including Plaintiff.

51. Defendants made the misrepresentation and/or actively concealed information concerning the safety and efficacy of Yasmin and YAZ with the intention and specific desire that the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiff, would rely on such in selecting Yasmin and YAZ as a contraceptive.

52. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of Yasmin and YAZ in their labeling, advertising, product inserts, promotional material or other marketing efforts.

53. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by Defendants, its sales representatives, employees, distributors, agents and/or detail persons.

54. Defendants knew that Plaintiff, her healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Yasmin and YAZ, as set forth herein.

55. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continue to misrepresent the potential risks and serious side effects associated with the use of Yasmin and YAZ.

56. Moreover, Defendants have a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drugs, including Plaintiff,

about the potential risks and serious side effects associated with the use of Yasmin and YAZ in a timely manner, yet they have failed to provide such warning.

Facts Specific to Plaintiff Courtney C. Blasius

57. Plaintiff was first prescribed YAZ by her healthcare provider on or about July 25, 2007.

58. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest YAZ to her detriment.

59. As a result of using Defendants' product YAZ, on or about September 12, 2007, Plaintiff began suffering serious and life-threatening side effects including, but not limited to, severe heart arrhythmias, cardiac arrest with a resulting anoxic brain injury, as well as other severe and permanent injuries, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses in excess of $1 million dollars, and the need for ongoing medical treatment, monitoring and/or medications over the course of her life.

60. Plaintiff did not discover, nor did she have any reason to discover, that her injury was a result of a defective drug and/or the wrongful conduct of Defendants, as set forth herein, any earlier than September 17, 2007.

COUNT ONE

Strict Products Liability - Defective Manufacturing

61. Plaintiff incorporates paragraphs 1 – 60 by reference.

62. Defendants are the manufacturers, designers, distributors, sellers, or suppliers of YAZ.

63. The YAZ birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were expected to and did reach the consumer without any alterations or changes.

64. The YAZ birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, were defective in their manufacture and construction when they left the hands of Defendants in that they deviated from product specifications such that the pills were unreasonably dangerous to an ordinary user or consumer and posed a serious risk of injury and death.

65. As a direct and proximate result of Plaintiff's use of YAZ as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

66. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiff's rights, so as to warrant the imposition of punitive damages.

COUNT TWO

Strict Products Liability - Design Defect

67. Plaintiff incorporates paragraphs 1 – 66 by reference.

68. Defendants are the manufacturers, designers, distributors, sellers or suppliers of YAZ.

69. The YAZ birth control pills manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were expected to and did reach consumers, including Plaintiff, without any alterations or changes.

70. The YAZ birth control pills manufactured and supplied by Defendants were defective in design or formulation in that, when the product left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect.

71. The foreseeable risks associated with the design or formulation of the YAZ birth control pills, include, but are not limited to, the fact that the design or formulation of YAZ is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

72. As a direct and proximate result of Plaintiff's use of YAZ as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

73. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarded Plaintiff's rights, so as to warrant the imposition of punitive damages.

COUNT THREE

Strict Products Liability - Defect Due to Inadequate Warning

74. Plaintiff incorporates paragraphs 1-73 by reference.

75. The YAZ birth control pills manufactured and supplied by Defendants were defective due to inadequate warning or instruction and were unreasonably dangerous to the ordinary user or consumer because Defendants knew or should have known that the product created significant risks of serious bodily harm and death to consumers, and they failed to adequately warn consumers and/or their healthcare providers of such risks.

76. The YAZ birth control pills manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instruction and were unreasonably dangerous to the ordinary user or consumer because, after Defendants knew or should have known of the risk of serious bodily harm and death from the use of YAZ,

Defendants failed to provide an adequate warning to consumers and/or their healthcare providers of the product, knowing the product could cause serious injury and death.

77. As a direct and proximate result of Plaintiff's use of YAZ as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages and economic loss in the future.

78. Defendants' actions and omissions as identified in this Complaint show that Defendants acted maliciously, with aggravated or egregious fraud, and/or intentionally disregarding Plaintiff's rights, so as to warrant the imposition of punitive damages.

COUNT FOUR

Negligence

79. Plaintiff incorporates paragraphs 1-78 by reference.

80. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of YAZ into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events.

81. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of YAZ into interstate commerce in that Defendants knew or should have known that the product caused such significant bodily harm or death and was not safe for use by consumers.

82. Defendants also failed to exercise ordinary care in the labeling of YAZ and failed to issue to consumers and/or their healthcare providers adequate warnings of the risk of serious bodily injury or death due to the use of YAZ.

83. Despite the fact that Defendants knew or should have known that YAZ posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market YAZ for use by consumers.

84. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

85. As a direct and proximate result of Defendants' negligence, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

86. Defendants' conduct as described above, including but not limited to its failure to adequately test YAZ, to provide adequate warnings, and its continued manufacture, sale and marketing of the product when it knew or should have known of the serious health risks it created, evidences malicious actions, aggravated or egregious fraud, and/or intentional disregard of the rights of Plaintiff, so as to warrant the imposition of punitive damages.

COUNT FIVE

Negligent Misrepresentation and/or Fraud

87. Plaintiff incorporates paragraphs 1-86 by reference.

88. Defendants are the manufacturers, designers, distributors, sellers or suppliers of YAZ and made representations to Plaintiff and her physician regarding the character or quality of YAZ for guidance in their decision to select YAZ.

89. Specifically, Defendants represented that their product was just as safe or safer, and just as effective or more effective, than other birth control products on the market.

90. Defendants' representations regarding the character or quality of YAZ were untrue.

91. Defendants had actual knowledge based upon studies, published reports and clinical experience that its product YASMIN created an unreasonable risk of serious bodily injury and death to consumers, or should have known such information.

92. Defendants negligently and/or intentionally misrepresented or omitted this information in product labeling, promotions and advertisements and instead labeled, promoted and advertised the product as safer and more effective than other types of oral contraceptives in order to realize profits from sales to consumers.

93. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to Plaintiff and her physician.

94. Plaintiff and her physician reasonably relied to her detriment upon Defendants' misrepresentations and/or omissions in the labeling, advertisements, and promotions concerning the serious risks posed by the product. Plaintiff reasonably relied upon Defendants' representations to her and/or her healthcare providers that YAZ was safer than other types of oral contraceptives for human consumption and/or use and that Defendants' labeling, advertisements and promotions fully described all known risks of the product.

95. As a direct and proximate result of Defendants' negligent and/or intentional misrepresentations or omissions, Plaintiff suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

96. Defendants' actions and omissions as identified in this Complaint demonstrate malicious actions, aggravated or egregious fraud, and/or intentional disregard of Plaintiff's rights so as to warrant the imposition of punitive damages.

COUNT SIX

Violation of the Vermont Consumer Fraud Statute

97. Plaintiff incorporates paragraphs 1-96 by reference.

98. Title 9 § 2461 of the Vermont Statutes Annotated authorizes the imposition of damages, attorney's fees and other remedies in favor of any consumer who relies upon the false or fraudulent representations of a defendant who is regularly and principally engaged in the business of selling goods to consumers.

99. Defendants were regularly and principally engaged in the business of selling pharmaceutical products to consumers, including YAZ.

100. As stated in detail in Count Five, Defendants made numerous false representations to Plaintiff and the public regarding the safety of YAZ, notwithstanding Defendants' knowledge of serious adverse side effects caused by these medications.

101. Despite Defendants' knowledge of the unsafe and dangerous nature of and YAZ, Defendants deceptively and knowingly failed to provide needed, accurate and adequate warnings and information regarding the health risks and hazards of YAZ to consumers such as Plaintiff who would reasonably and foreseeably use these medications.

102. Defendants' conduct as alleged herein was wanton, or done with malice or ill will.

103. Plaintiff believed and justifiably relied upon Defendants' representations and misrepresentations when she used YAZ.

104. As a direct and proximate cause of Defendants' consumer fraud, Plaintiff suffered cardiac arrest, resulting in anoxic brain injury, as well as other severe and permanent injuries, physical pain and mental anguish, diminished enjoyment of life, medical, health

and related expenses in excess of $1 million dollars, and the need for ongoing medical treatment, monitoring and/or medications over the course of her life.

WHEREFORE, Plaintiff Courtney C. Blasius requests the court to enter judgment in her favor against Defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer Schering Pharma AG, Bayer Corporation, Bayer HealthCare LLC, Bayer Pharmaceuticals Corporation, Berlex Laboratories, Inc., Berlex, Inc., and Bayer AG, jointly and severally, in amounts to be determined for compensatory damages, punitive damages, attorneys' fees, interest, costs, and such other relief as may be just and proper.

JURY TRIAL DEMAND

Plaintiff demands trial by jury on all issues for which she is entitled to a jury trial as a matter of right.

Dated: May 10, 2010

/s/ Samuel W. Lanham, Jr.___
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